



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

DEC 16 1998

2071 '99 JAN -4 P2:59

Mr. Paul Dube  
CEO  
Optima Laboratories, Inc.  
39 Dodge Street  
Suite 108  
Beverly, Massachusetts 01915

Dear Mr. Dube:

This is in response to your letter of December 10, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Optima Laboratories, Inc. is making the following statements, among others, for the products **Optima Fiber Plus** and **Optima Calcium Plus**:

"...reduces harmful bacteria..."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for these products suggest that they are intended to treat, prevent, mitigate, or cure diseases, namely, diseases caused by pathogenic microorganisms. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

975-0163

LET 249

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, New England District Office, Office of Compliance, HFR-NE240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

f/t:HFS-456:rjm:12/15/98:docname:62762.adv:disc34



Office of Special Nutritionals  
Food and Drug Administration  
Center for Food Safety and Nutrition  
200 C Street S.W.  
Washington D.C. 20204

December 10, 1998

I wish to certify that the information provided relative to the two brand name products identified below are complete and accurate, and that Optima Laboratories, Inc. has substantiation that the statements provided are truthful and not misleading.

Authorized Representative: \_\_\_\_\_

Paul Dube - CEO

1) Name and address of distributor of two brand name products identified below:

Optima Laboratories, Inc.  
39 Dodge Street, Suite 108  
Beverly, MA 01915

2a) Brand Name: Optima Fiber Plus

b) Structure/ Function Claim Statement:

i) "Selectively promotes the growth of friendly bacteria and reduces harmful bacteria for well-balanced intestinal flora"

c) Ingredient subject to claim: fructooligosaccharides

3a) Brand name: Optima Calcium Plus

b) Structure/ Function Claim Statement:

i) "Selectively promotes the growth of friendly bacteria and reduces harmful bacteria for well-balanced intestinal flora and enhanced calcium absorption"

c) Ingredient subject to claim: fructooligosaccharides

4a) Brand name: Optima Calcium Plus

b) Structure/ Function Claim Statement

" Provides the recommended daily allowance of Calcium, Vitamin D & Magnesium for maintaining strong bones & healthy nervous system"

4c) Ingredients subject to claim: i) Calcium as calcium carbonate, calcium citrate, and patented Citrimal® citrate, malate, glycinate

ii) Magnesium as magnesium oxide, magnesium citrate, and patented Chelazome® glycinate

iii) Vitamin D as Cholecalciferol